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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/063,937 | 05/28/2002 | Brent C. Gerberding | S63.2-10447 | 2387 |

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VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HOUSTON, ELIZABETH

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/063,937 | Applicant(s) GERBERDING, BRENT C. | |
| | Examiner Elizabeth Houston | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-33 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/9/02, 7/18/02</u> | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> |

Continuation of Attachment(s) 6). Other: IDS Mail Date: 10/15/03, 9/13/04.

Attachment A: USPN 6,652,579, Fig. 6

Attachment B: USPN 6,730,116, Fig. 8

DETAILED ACTION

Oath/Declaration

1. The Oath/Declaration seems to be missing. Examiner respectfully requests the lawyer to verify this information to ensure that this is not an oversight on the part of the USPTO.

Specification

2. Paragraph 84 is conflicting with respect to claim dependency. The paragraph calls for multiple dependency forms of the claims and the claims clearly state single dependency forms. Therefore, Paragraph 84 must be removed from the specification.

3. The disclosure is objected to because of the following informalities: typos.

- a. Para. 3: A stents should be – A stent.
- b. Para. 11,15,18: both ends of the strut should be – both ends of the medical device.
- c. Para. 26: ends of a connecting struts should be – ends of connecting struts.
- d. Para 28: radiopaque region present a width should be clarified.
- e. Para 29: the curvature the struts should be – the curvature of the struts.
- f. Para 36: of other of the struts should be – of the other struts.
- g. Para 38: that the regions should be – that of the regions.
- h. Para 46: second regions than in the remainder should be clarified.
- i. Para 47: one special stents should be – one special stent
- j. Para 50: ends of the stens should be – ends of the stent

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-2, 6, 8-9, 11-12, 15-17, 21-24, 26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et. al. (USPN 6,652,579). Cox clearly teaches a stent having a longitudinal axis, comprising a plurality of interconnected struts (Figs. 1-15) with at least one special strut (54) with enlarged width (Col. 7, line 16), having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 3, line 14) between the two regions. There are a plurality (Attachment A 54a-54d) of special struts, which are located between the ends of the stent; one special strut (54d) is located at one end of the stent; and one special strut (54b or 54c) is located anywhere between the middle of the stent and halfway from the middle to the end of the stent. Cox further teaches a stent wherein at least two struts on either side of the special strut have a curvature, which is complementary to that of the special strut and wherein the curvature decreases as the distance from the special strut increases (Attach. A, 1 and

2). Cox also teaches a stent in unexpanded form (Fig.1), which has a central strut in the middle of the stent that is nested between two other struts; the circular portion of the strut being more radiopaque than the linear portion of the strut (Col. 3, line 14). Cox further states that the radiopaque marker can be any shape that provides for increased surface area (Col.7, line 18), including circular (Figs. 1-6) or bulbous (Figs. 13-15).

6. Claims 1-2, 6, 9-17, 21-24, 26, 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolinsky et. al (USPN 6,730,116). Wolinsky clearly teaches a stent having a longitudinal axis, comprising a plurality of interconnected struts (Figs. 1-14) with at least one special strut (Fig. 3, 28 and Fig. 8, 62a) with enlarged width, having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 6, line 67) between the two regions. There are a plurality of special struts, which are located between the ends of the stent (Fig. 8, 62a and b); wherein one special strut (62a) is located at one end of the stent, and one special strut (62b) is located at the other end (Col. 8, line 58). Wolinsky further teaches a stent wherein at least two struts on either side of the special strut have a curvature that is complementary to that of the special strut and wherein the curvature decreases as the distance from the special strut increases (Attach. B, 1 and 2). Wolinsky also teaches a stent in unexpanded (crimped) form (Col. 7, Line 3) (Fig. 8) which has a plurality of central struts (62a, 62b) circular in form (Col. 7, line 4) that is nested between two other struts; the circular nested portion of the strut being more radiopaque than the linear portion of the strut (Col. 6, line 67).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 25 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Thornton et. al (USPN 6,551,350). Cox meets the claim limitations as stated above but fails to disclose a stent in bifurcated form.

9. Thornton teaches a stent in bifurcated form as shown in Fig. 15. Thornton further teaches that a bifurcated stent is necessary when a defect, such as an aneurysm, is located very close to the bifurcation of a trunk lumen into branch lumens. Without a bifurcated stent, treatment becomes difficult because neither the trunk lumen nor the branch lumens provides a sufficient portion of healthy lumen wall on both sides of a defect to which a straight single lumen stent can be secured (Col. 1, paragraphs 6-8).

10. It would have been obvious to one skilled in the ordinary art at the time of the invention to design a radiopaque stent in bifurcated form. Thornton provides the motivation for the combination in that it is necessary to treat aneurysms and defects located close to the bifurcation of a trunk lumen into branch lumens. The inventions are analogous with each other and the instant invention, and so the combination is proper.

11. Claims 3-5, 7, 18-20, and 32-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Erbel et. al. (USPN 6,730,116). Wolinsky meets

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the claim limitations as stated above. Wolinsky further teaches, "stents can be used to repair aneurysms" (Col. 1, line 36). Wolinsky fails to teach a stent with a cover.

12. Erbel discloses an endovascular prosthesis (Fig. 3) or stent comprising an annular portion with a porous section (20) and a nonporous section (25). As to claims 4-5, 19-20, and 32-33, the nonporous section (25) or cover is disposed about the circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para 70-72).

13. As to claims 3, 7, 18, Erbel discloses a cover disposed about the stent in a region including radiopaque markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).

14. The inventions are analogous with each other and with the instant invention therefore a combination is proper. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers, which extends circumferentially about the stent but does not cover the entirety of the stent. Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it could then be used to treat aneurysms and tears. Further using the cover at the location of the radiopaque markers augments the ease of use.

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15. Claims 13 and 14 are rejected to as Product by Process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). (See MPEP § 2113) As stated above, the product is clearly anticipated by Cox and Wolinsky and so claims 13 and 14 are unpatentable even though the prior art was made by a different process.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

11/11/04

